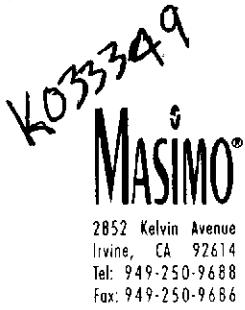


510(k) SUMMARY

JAN 28 2004



Submitted by: Masimo Corporation
2852 Kelvin Ave
Irvine, CA 92614-5826
(714) 250-9688
FAX (714) 250-9686

Company Contact: James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance

Date Summary Prepared: October 17, 2003

Trade Name AC-1 Adapter Cable

Common Name Cable, Transducer and Electrode

Classification Name and Product Code: Cable, Transducer and Electrode (74DSA) (870.2900)

Substantially Equivalent Devices: Masimo SET[®] Radical Pulse Oximeter with SatShare[™] and LNOP[®] series of Sensors and Cables
510(k) Number - K031330
Nellcor N-395 Pulse Oximeter – K991823
Nellcor N-200 Pulse Oximeter – K863784

Device Description

The AC-1 Adapter Cable is fully compatible oximetry cable that allows the use of Masimo LNOP Sensors with Nellcor and Nellcor compatible pulse oximeter monitors. The cable represents a design change to the Masimo patient cables.

The AC-1 Adapter Cable is similar in construction to the predicate device enabling the Masimo LNOP Sensors to be connected to Nellcor and Nellcor compatible pulse oximeter monitors.

Intended Use

The AC-1 Adapter Cables used with Masimo LNOP Sensors are intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor) for adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Technology Comparison

The AC-1 Adapter Cables used with Masimo LNOP Sensors are substantially equivalent in intended use, design, principles of operation, materials, and performance to predicate sensors and operate on identical principles of non-invasive optical assessment of tissue oxygenation using emitters and detectors.

0052

510(k) SUMMARY

The AC-1 Adapter Cable is designed, configured, and manufactured for full compatibility with Nellcor and Nellcor compatible pulse oximeters using Masimo LNOP Sensors. The AC-1 Adapter Cable is constructed of similar materials and components of equivalent specifications as used in the predicate devices.

The accuracy of the AC-1 Adapter Cables used with Masimo LNOP Sensors is equivalent to those of the predicate devices.

Performance Testing

Environmental Testing

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed

Clinical Testing

Clinical studies were performed using the AC-1 Adapter Cables used with Masimo LNOP Adult oximetry sensors on healthy adult volunteer subjects during no motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter. Clinical testing of the SPO2.COM Adult and Reusable sensors resulted in an accuracy of less than 2% $\text{SpO}_2 \text{ A}_{\text{RMS}}$ in the range of 70%-100% SaO_2 for adults, pediatrics and infants and less than 3% A_{RMS} for neonates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2004

Mr. James J. Cronin
Vice President, Regulatory Affairs/Quality Assurance
Masimo Corporation
2852 Kelvin Avenue
Irvine, California 92614-5826

Re: K033349
Trade/Device Name: AC-1 Adapter Cable
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: January 21, 2004
Received: January 22, 2004

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. James J. Cronin

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033349

Device Name: AC-1 Adapter Cable

Indications For Use:

The AC-1 Adapter Cable with Masimo sensors are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate (measured by an SpO₂ sensor) for use with adult, pediatric, infant, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033349

0037